

AMENDED IN SENATE MAY 31, 2005

AMENDED IN SENATE MAY 23, 2005

AMENDED IN SENATE APRIL 26, 2005

Senate Constitutional Amendment

No. 13

**Introduced by Senators Ortiz and Runner
(Coauthors: Senators Cox and Dutton)**

(Coauthors: Assembly Members Benoit, Garcia, Jones, Laird, Leno,
and Yee)

March 17, 2005

Senate Constitutional Amendment No. 13—A resolution to propose to the people of the State of California an amendment to the Constitution of the State, by amending Section 6 of, and by adding Sections 8 and 9 to, Article XXXV thereof, relating to biomedical research.

LEGISLATIVE COUNSEL'S DIGEST

SCA 13, as amended, Ortiz. Biomedical research.

The California Stem Cell Research and Cures Act, an initiative measure, establishes the California Institute for Regenerative Medicine, the purpose of which is, among other things, to make grants and loans for stem cell research, for research facilities, and for other vital research opportunities to realize therapies, protocols, and medical procedures that will result in the cure for, or substantial mitigation of, diseases and injuries. Existing law authorizes the issuance of bonds, not to exceed \$3,000,000,000, for the purpose of funding this research.

Existing law establishes the Independent Citizen's Oversight Committee (ICOC), composed of appointed members, that is required to perform various functions and duties with regard to the operation of

the institute. Existing law also establishes various working groups whose purposes are to make recommendations to the ICOC regarding the making of these grants and loans.

This measure would require the chair and vice chair and any appointed member of the Independent Citizen's Oversight Committee (ICOC), the president and each employee of the institute, and any member of any working or advisory group appointed to assist the institute or its governing body to disclose his or her income investments, and interests in real property in the manner set forth in the Political Reform Act, or its successor, and except for employees of the institute *and any member of any working or advisory group appointed to assist the institute or its governing body*, to divest themselves of, or place into a blind trust, any financial or real property interest held by that person in any organization that applies for funding from, or contracts with, the institute or in any organization with a substantial interest in stem cell therapy. It would also require *the State Auditor to review the financial disclosures made by each member of a working or advisory group, in addition to the voting record of each member regarding recommendations for applications for research and facility grants and loan awards and regulatory standards, and submit an annual report to the Legislature containing findings on whether any of the votes made by these members may constitute, or have constituted, a conflict of interest, as defined.*

This measure would require that records and meetings be subject to state open meeting and public record laws that are applicable to state agencies, with certain exceptions.

This measure would require every contract, award, grant, loan, or other arrangement entered into by the institute or the ICOC to ensure that these financial arrangements do not result in a gift of public funds, that loan, lease, or rental arrangement terms are consistent with or below market rates for rent or interest, and that any clinical treatments, products, or services resulting from the biomedical research are made available, at the costs of producing them, to California residents who are eligible to receive assistance through state and county health care and preventive health programs.

The measure would require these financial arrangements to provide that the state recoup the full amount of its legal and administrative costs incurred with respect to patenting and licensing activities related to biomedical research, would require that the state be provided with its share of royalties or licensing revenues, derived from the

development of clinical treatments, products, or services resulting from the research, that is sufficient to repay its expenses incurred in developing these treatments, products, or services, and would also require that these royalties or licensing revenues be transmitted to the state in an amount sufficient to repay the costs of issuing bonds incurred by the state in funding the biomedical research.

Vote: $\frac{2}{3}$. Appropriation: no. Fiscal committee: yes.

State-mandated local program: no.

Resolved by the Senate, the Assembly concurring, That the Legislature of the State of California at its 2005-06 Regular Session commencing on the sixth day of December 2004, two-thirds of the membership of each house concurring, hereby proposes to the people of the State of California, that the Constitution of the State be amended as follows:

First—That Section 6 of Article XXXV thereof is amended to read:

SEC. 6. Except as otherwise provided in this article, notwithstanding any other provision of this Constitution or any law, the institute, which is established in state government, may utilize state issued tax-exempt and taxable bonds to fund its operations, medical and scientific research, including therapy development through clinical trials, and facilities.

Second—That Section 8 is added to Article XXXV thereof, to read:

SEC. 8. (a) The chair and vice chair and any appointed member of the Independent Citizen's Oversight Committee (ICOC), *and* the president and each employee of the institute; ~~and any member of any working or advisory group appointed to assist the institute or its governing body~~ shall disclose his or her income, investments, and interests in real property in the manner set forth in Chapter 7 (commencing with Section 87100) of Title 9 of the Government Code, or its successor. The chair and vice chair and any appointed member of the ICOC, *and* the president of the institute; ~~and any member of any working or advisory group appointed to assist the institute or its governing body~~ shall divest themselves of or place into a blind trust, any financial or real property interest held by that person in any organization that applies for funding from, or contracts with, the institute or in any organization with a substantial interest in stem cell therapy. An

1 organization with a substantial interest in stem cell therapy is one
2 for which, based upon publicly available information, more than
3 five percent of the ~~organizations~~ organization's current annual
4 research budget is allocated to stem cell therapy.

5 (b) (1) Upon his or her appointment and each year at a time
6 specified by the ICOC, each member of a working or advisory
7 group appointed to assist the institute or its governing body shall
8 disclose to the ICOC his or her income, investments, and interest
9 in real property in the manner set forth in Chapter 7
10 (commencing with Section 87100) of Title 9 of the Government
11 Code, or its successor. The ICOC shall provide the disclosures to
12 the State Auditor. The State Auditor, or his or her successor,
13 shall review the disclosures, in addition to the voting record of
14 each working or advisory group member regarding
15 recommendations for applications for research and facility
16 grants and loan awards and regulatory standards, and submit an
17 annual report to the Legislature containing findings on whether
18 any of the votes made by these members may constitute, or has
19 constituted, a conflict of interest that requires or required the
20 member to recuse himself or herself from consideration of an
21 application or standard if the member is otherwise required
22 under existing law to recuse himself or herself.

23 (2) For purposes of this subdivision, "conflict of interest"
24 means the working or advisory group member, or a close relative
25 or professional associate of the member, has a financial or other
26 interest in an application or standard that is known to the
27 member, including a direct benefit of any amount deriving from
28 an application or standard, or a financial benefit of any type
29 from an applicant institution of over five thousand dollars
30 (\$5,000) per year, including honoraria, fees, stock, or other
31 benefits. For purposes of this paragraph, "close relative" and
32 "professional associate" shall have the same meaning as those
33 terms are defined under the National Institutes of Health
34 Conflict of Interest, Confidentiality and Non Disclosure Rules.

35 ~~(b)~~

36 (c) (1) Except as provided in ~~paragraph (2)~~ paragraphs (2),
37 (3), and (4), meetings and records of the institute, the ICOC, or
38 any body established to govern the institute, and any working or
39 advisory group, are subject to California open meeting and public
40 record laws that are applicable to state agencies.

~~(2) Notwithstanding paragraph (1), the ICOC, any body established to govern the institute, and any working group or advisory group, may conduct a closed session for the purpose of~~

(2) Notwithstanding paragraph (1), any working or advisory group appointed to assist the institute or its governing body that is charged with reviewing and recommending medical research projects for funding may hold closed sessions when necessary to conduct or carry out scientific peer review of any research project submitted for funding, or for the purpose of considering or discussing matters involving intellectual property or proprietary information and matters involving prepublication confidential scientific information associated with individual research proposals submitted for funding. However, any working or advisory group that is charged with reviewing and recommending medical research projects for funding shall produce a written summary that shall be a public record of the reasons for recommending or not recommending any project for funding as well as how each project recommended for funding will benefit residents of California. The working or advisory group shall hold an open session to allow public comment on its decision prior to submitting any recommendation to the ICOC.

(3) Notwithstanding paragraph (1), the institute, ICOC, or any body established to govern the institute, and any working group or advisory group, may conduct closed sessions as permitted by the Bagley-Keene Open Meeting Act (Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code), or its successor.

(4) Notwithstanding paragraph (1), records containing intellectual property or proprietary information and matters involving prepublication of confidential scientific information shall not be subject to public record laws.

Third—That Section 9 is added to Article XXXV thereof, to read:

SEC. 9. (a) Every contract, award, grant, loan, or other arrangement entered into by the institute or the Independent Citizen's Oversight Committee shall ensure all of the following:

(1) Notwithstanding Section 6, the contract, award, grant, loan, or other arrangement does not result in a gift of public funds within the meaning of Section 6 of Article XVI.

1 (2) All clinical treatments, products, or services resulting from
2 the biomedical research are made available at the costs of
3 producing them to California residents who are eligible to receive
4 assistance through state and county health care and preventive
5 health programs including, but not limited to, the Medi-Cal and
6 Healthy Families programs.

7 (3) The terms of any loan, lease, or rental arrangement are
8 consistent with, or below, market rates for rent or interest.

9 (4) The State recoups the full amount of its legal and
10 administrative costs incurred with respect to patenting and
11 licensing activities related to the biomedical research.

12 (5) The State is provided a share of the royalties or revenues,
13 derived from the development of clinical treatments, products, or
14 services resulting from the research, that is sufficient to repay its
15 expenses incurred in developing the clinical treatments, products,
16 or services.

17 (6) In addition to royalties or licensing revenues described in
18 paragraph (5), royalties or licensing revenues are transmitted to
19 the State in an amount sufficient to repay any costs of issuing
20 bonds incurred by the State in funding the biomedical research.

21 (b) Nothing in this section shall be construed to preclude the
22 State from receiving any other benefits to which it would
23 otherwise be entitled under Chapter 3 (commencing with Section
24 125290.10) of Part 5 of Division 106 of the Health and Safety
25 Code, or its successor.